UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL No. 16-2738 (MAS) (RLS)**
THIS DOCUMENT RELATES TO ALL CASES	

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT LLC'S MOTION TO EXCLUDE THE OPINIONS OF DRS. DAVID KESSLER, LAURA PLUNKETT, WILLIAM SAGE, AND GEORGE E. NEWMAN

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INTRODUCTION

On July 23, 2024, Defendants Johnson & Johnson and LLT Management (hereinafter "Defendants" or "J&J") moved to exclude the testimony of Plaintiffs' experts, David Kessler, M.D., J.D., Laura Plunkett, Ph.D., William Sage, M.D., J.D., and George E. Newman, Ph.D.[1] Plaintiffs' experts offer proper expert opinions that are relevant and reliable under Fed. R. Evid. 702 and are based on reliable methodologies within their areas of expertise. Accordingly, Plaintiffs respectfully request that this Court deny Defendants' Motion to Exclude and permit the testimony of Plaintiffs' experts.

EXPERTS' BACKGROUNDS

A. David Kessler, M.D., J.D.[2]

Dr. Kessler currently serves as professor of Pediatrics and Epidemiology and Biostatistics at University of California, San Francisco. Dr. Kessler has previously held teaching positions at Albert Einstein School of Medicine, Columbia University School of Law, and Yale University School of Medicine. A medical

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[1] Defendants Johnson & Johnson and LLT Management, LLC's Memorandum of Law in Support of Motion to Exclude the Opinions of Drs. David Kessler, Laura Plunkett, William Sage, and George Newman, ECF No. 33000-2 (hereinafter "Defs.' Mot.")

[2] Dr. Kessler's Amended Expert Report, including his CV, is attached as **Exhibit 1**. Dr. Kessler's Deposition, taken on April 8, 2024, is attached as **Exhibit 2**.

doctor and attorney, Dr. Kessler received his M.D. from Harvard Medical School, his J.D. from the University of Chicago, and did his residency in pediatrics at Johns Hopkins University.

In 1990, Dr. Kessler was appointed by President George H.W. Bush as Commissioner of the United States Food and Drug Administration, reappointed by President Bill Clinton, and served in that position for seven years until retiring in 1997. As FDA Commissioner, Dr. Kessler oversaw all centers of the FDA, including the Center for Food Safety and Applied Nutrition, which was responsible for cosmetic regulation, and the National Center for Toxicological Research. During his time at the FDA, Dr. Kessler was instrumental in tackling critical public health issues such as the AIDS epidemic (including the development and approval of medications to treat HIV/AIDS), regulation of cigarettes, and the moratorium on silicone breast implants. He was awarded the Public Welfare Medal from the National Academy of Sciences in 2001.

From 2021 to 2023, Dr. Kessler served as Chief Science Officer of the United States Covid-19 Response and co-led what was known as Operation Warp Speed to facilitate the development, manufacturing, and distribution of the COVID-19 vaccines.

Dr. Kessler taught food and drug law at Columbia University Law School and has testified many times before Congress on food, drug, and consumer

protection issues under federal and state law. Over the last forty years, he has published many articles in legal, medical, and scientific journals on the federal regulation of food, drugs, and medical devices. He has also served as an advisor and on the boards of pharmaceutical and biomedical companies, advising these companies on the standards applicable in the industry and ensuring compliance with FDA regulations.

In his report, Dr. Kessler summarizes his opinions in light of his qualifications as follows:

> My opinions in this case focus on the responsibilities of cosmetic manufacturers, focusing on the regulatory interface between cosmetic manufacturers and the FDA, as well as industry standards. I have not been asked to opine on causation issues. I have been asked to address the duties and conduct of defendant cosmetic companies in the face of a potential health hazard. In formulating my regulatory and safety opinions in this case, reviews of the epidemiology, laboratory testing methodology, chemical and geological relationship between talc and asbestos, health consequences with asbestos and elongated mineral particles, and product formulation and manufacturing were performed. The approach and methods utilized here are consistent with those I have taken to address regulatory questions in academia, my work as a government official, and as a board member advising corporate entities for over forty years.[3]

Dr. Kessler's report and testimony in this case focus on an area in which Dr. Kessler has the requisite experience to testify about the regulation of talcum

[3] Kessler Report at 5-6.

powder products, including Johnson's Baby Powder.

B. Laura Plunkett, Ph.D., DABT[4]

Dr. Plunkett is a pharmacologist,[5] toxicologist,[6] and FDA regulatory specialist. She is a partner at BioPolicy Solutions, LLC, a consulting company that advises clients in biological science, regulatory affairs, and business decisions about the development and marketing of existing products as well as new technologies.

Dr. Plunkett received her Ph.D. in Pharmacology from the University of Georgia, College of Pharmacy, and is board certified as a Diplomate of the American Board of Toxicology (DABT). She has over twenty years of experience in pharmacology and toxicology and has worked in both government and academic research. She has taught pharmacology and toxicology to undergraduate students, medical students, law students, pharmacy students, and other post-graduate students.

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[4] Dr. Plunkett's 3d Amended Expert Report, including her CV at Appendix A, is attached as **Exhibit 3**. Dr. Plunkett's most recent MDL deposition, taken on December 21, 2023, is attached as **Exhibit 4**.

[5] Pharmacology is the study of how substances interact with living organisms to produce a change in function. Goodman & Gilman's The Pharmacological Basis of Therapeutics (Alfred G. Gilman et al. eds., 6th ed. 1980).

[6] Toxicology is the study of the adverse effects of xenobiotics, or chemicals, on living organisms. It is the study of symptoms, mechanisms, treatments, and detection of poisoning, especially the poisoning of people. Casarett & Doull's Toxicology: The Basic Science of Poisons (Curtis D. Klaassen ed., 7th ed. 2008).

Dr. Plunkett has worked as an industry consultant and regulatory expert for over 25 years.[7] Among other things, that work includes projects dealing with regulation of products by the FDA; designing preclinical and clinical studies for efficacy and safety; and advising clients regarding efficacy and warnings for products based on labeling regulations.[8] Her consulting work also involves screening work with heavy metals, such as lead, mercury, cadmium, and arsenic.[9] She has consulted with manufacturers of cosmetic ingredients and cosmetic products throughout her non-academic career. In the 1990s, Dr. Plunkett served as a consultant for condom manufacturers, providing scientific advice on the safety of talcum powder used on the surfaces of the devices as a dry lubricant.[10] Her consulting work includes routine interactions with the FDA as an agent for her clients.[11]

Common to all Dr. Plunkett's work as a consultant is the tool and generally accepted methodology of Risk Assessment.[12] This includes many projects where risks related to exposure to chemicals in consumer products is at issue.[13] As part of

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7 *Id*. at ¶7.
8 *Id*. at ¶6.
9 Plunkett Dep. at 32:22-33:13.
10 *Id.*
11 *Id.* at 37:9-24.
12 Plunkett Report at ¶6.
13 *Id.*

her Risk Assessment work, she commonly reviews and relies upon epidemiology data, as well as animal and in vitro data to assess risks to human health.[14]

As part of her consulting work, Dr. Plunkett is regularly called upon to determine whether a product is "generally recognized as safe" or "GRAS."[15] These determinations are much like the reviews performed on cosmetic ingredients by members of the Cosmetic Ingredient Review ("CIR") panel, in that they involve "consideration of animal and human toxicity data, cellular and mechanistic data, human product experience reports, and the type and level of exposure that may occur when humans are exposed to the ingredient or product."[16]

Dr. Plunkett has published dozens of peer-reviewed articles on issues related to pharmacology and toxicology, as well as a book chapter on FDA pharmacovigilance practices.[17] She has served as a peer-reviewer for medical journals.[18] She has experience in pharmacokinetics,[19] where she has designed

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14 *Id.*

15 *Id.* at ¶8.

16 *Id.*

17 *Id.* at ¶9.

18 *Id.*

19 Pharmacokinetics is the study of "the process by which a drug is absorbed, distributed metabolized and eliminated by the body." American Heritage Dictionary (2007). It is the "study of the actions of a drug in the body, which can, in many respects, be envisioned as the actions of the body on an administered drug, it includes the studies of mechanism of drug absorption, distribution, metabolism, and excretion; onset of action; duration of effect; biotransformation, and effects of excretion of the metabolites of the drug." Mosby's Medical Dictionary, 8th ed. (2009).

clinical trials and analyzed pharmacokinetic data.[20] She is an expert in "mechanisms that have been associated with an increased risk of cancer in . . . human cells and tissues."[21]

In summary, her specialized knowledge, skill, experience, training, and education qualify her to testify about pharmacology, toxicology, pharmacokinetics, human health risk assessment, and the regulation of cosmetic products in the United States.

C. William Sage, M.D., J.D.[22]

Dr. Sage is a tenured Professor of Law at Texas A&M University School of Law, a tenured Professor of Translational Medical Science at Texas A&M University School of Medicine, a professor by courtesy at the Bush School of Government and Public Service at Texas A&M University, and an Assistant Vice President in the Texas A&M University Health Science Center. He has also held teaching positions over the years at Columbia University, Yale University, Harvard University, New York University, Duke University, Emory University, and George Washington University. In these positions, he has taught classes on regulatory

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20 *Id.*

21 Plunkett 2023 Dep. 113:13-15.

22 Dr. Sage's Amended Expert Report, including his CV, is attached as **Exhibit 5**. Dr. Sage's deposition, taken on September 23, 2021, is attached as **Exhibit 6**.

theory and public policy, professional ethics and self-governance, and health law and policy.

Dr. Sage received his undergraduate degree from Harvard College and then received both his M.D. and J.D. from Stanford University. He also holds an honorary doctorate from Universite Paris Descartes. He interned at Mercy Hospital in San Diego and then completed his residency at Johns Hopkins. Before his academic career, Dr. Sage practiced corporate law at O'Melveny & Myers.

Dr. Sage is also an elected member of the National Academy of Medicine (one of the three constituent academies of the National Academies of Science)[23] and the American Law Institute. He also has served on numerous advisory boards for journals and organizations in the field of health law.

Dr. Sage has published extensively on health law in the United States. He has written or edited 4 books. Notably, he is the co-editor of the most recent edition of one of the preeminent treatises on health law, the Oxford Handbook of U.S. Health Law. He has also written 30 book chapters and published over 200 articles, many of which address health law and policy issues directly relevant here.

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[23] National Academy of Medicine, *About the National Academy of Medicine,* available at https://nam.edu/about-the-nam/, last accessed August 21, 2024 ("Founded in 1970 as the Institute of Medicine (IOM), the National Academy of Medicine (NAM) is one of three academies that make up the National Academies of Sciences, Engineering, and Medicine (the National Academies) in the United States. The NAM has more than 2,400 members elected by their peers in recognition of outstanding achievement.").

Throughout his career, Dr. Sage has received grants from various health-focused organizations, including one founded and funded by Johnson & Johnson – the Robert Wood Johnson Foundation.

Dr. Sage describes his expertise relevant to this case in his report as follows:

> My expertise is in the science of policymaking, including the science of regulatory design. I have particular expertise in the regulation of health and safety, in information-based regulation, and in self-regulatory models. Self-regulation in which I am expert includes government-supervised health and financial self-regulation, corporate compliance and corporate governance, and the regulation of self-governing professions.[24]

Dr. Sage is qualified to opine on the regulatory practices and standards under which cosmetics manufacturers operate and whether Defendants complied with these standards in the development, manufacture, marketing, and sale of Talcum Powder Products—all of which will assist the jury.

D. George E. Newman, Ph.D.[25]

Dr. Newman is an Associate Professor of Organizational Behavior in Human Resource Management and Marketing at Rotman School of Management, University of Toronto where he teaches Introduction to Organizational Behavior. Dr. Newman was previously an Associate Professor of Management and

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[24] Sage Report at 2.

[25] Dr. Newman's Expert Report, including his CV, is attached as **Exhibit 7**. Dr. Newman's deposition, taken on May 15, 2024, is attached as **Exhibit 8**.

Marketing at Yale School of Management. Dr. Newman has taught courses at Yale and the University of Toronto in marketing, consumer behavior, and marketing management at the undergraduate and graduate levels (MBA and Ph.D.).[26]

In addition to his teaching and research obligations at the University of Toronto and Yale University, Dr. Newman has served as a Visiting Professor of Marketing at New York University, the University of Hawaii, and Seoul National University.[27] He has also taught seminars on the topics of marketing and management to executives in senior leadership positions in industry and the U.S. federal government.[28] He has been a keynote speaker at the Association of National Advertisers' National Convention[29] and regularly serves as an invited speaker and moderator at universities including Harvard, Stanford, Columbia, MIT, the Wharton School, the University of Chicago, Northwestern University, Carnegie Mellon, and London Business School.[30] Dr. Newman has served on the

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26 *Id*. at 3.

27 *Id.*

28 *Id.*

29 *Id.* The Association of National Advertisers ("ANA") was founded in 1910 and is the advertising industry's largest and oldest trade association, established for the purpose of promoting cooperative relationships between regional and national advertising industries, manufacturers and dealers, and advertisers and agencies. The ANA's Code of Ethics can be viewed here: https://www.ana.net/content/show/id/accountability-chan-ethicscode-final#bookmark11 (last visited Aug. 19, 2024).

30 Newman Report at 3.

editorial boards for both the *Journal of Consumer Psychology* and the *Journal of Sustainable Marketing*.[31]

Dr. Newman earned his Ph.D. in Cognitive Psychology from Yale University in 2008.[32] He also received M.Phil. (2006) and M.S. (2005) degrees in Psychology at Yale University.[33] Dr. Newman's training is in cognitive psychology, the study of thinking, which is the basis for his work in the area of branding and consumer behavior. Consumer behavior examines the psychological and strategy issues related to marketing. It is taught from the perspective of the consumer and assists in understanding the nature of consumer perceptions and how they intersect with company marketing strategies.[34]

Dr. Newman's focus on the academic field of consumer behavior combines the disciplines of marketing science, consumer research, and behavioral economics. Consumer behavior is distinguished from other fields by its focus on a consumer role, emphasizing the acquisition, consumption, and disposal of marketplace products, services, and experiences.[35] The use of experiment and scientific methods has been widespread in the study of consumer behavior since

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31 *Id.*

32 *Id.*; *Id.* at 1.

33 *Id.* at 3; *Id.* at 1.

34 Newman Dep. at 38:12-18.

35 MacInnis, D. J., & V.S. Folkes (2010). "The disciplinary status of consumer behavior: A sociology of science perspective on key controversies." *Journal of consumer research*, *36*(6), 899-914.

the early 20th century, but quantitative approaches to understanding the bases of consumer perceptions, behavior, and choice can be traced back far earlier.[36]

Dr. Newman has published more than 60 peer-reviewed articles and 10 book chapters,[37] writing and opining extensively on the topics of marketing communications, brand heritage, brand authenticity, consumer perceptions of trust, and corporate social responsibility.[38] He has published in the top-tier journal of the American Marketing Association – the *Journal of Marketing Research*.[39] He has also published papers relevant to how consumers interpret and weigh information related to health risks.[40]

"The Curse of the Original: How and when heritage branding reduces consumer evaluations of enhanced products" documents a consumer backlash toward heritage brands that alter their flagship products, which is directly relevant to J&J's decision to not replace Johnson's Baby Powder with its cornstarch

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36 Strigler (1954). "The Early History of Empirical Studies of Consumer Behavior." *Journal of Political Economy*, 62(2), 95-113.

37 Newman Report at 3; *see also* Newman CV.

38 Newman Report at 3.

39 *See* Newman CV, Publications at ¶ 27. Founded in 1937, the American Marketing Association ("AMA") is one of the oldest and largest associations catering to marketing executives and their companies, with over 30,000 members, 70 local chapters in the United States, and 350 affiliate chapters around the world. *See* https://www.ama.org (last visited, August 19, 2024). Ethical practices relating to advertising have been promulgated by the AMA and can be found here: https://www.ama.org/ama-statement-of-ethics (last visited Aug. 19, 2024).

40 *See* Newman Dep. 207:7-15, May 15, 2024.

alternative.[41] The article notes another J&J similarity: "Brands often try to increase demand for their flagship products through the use of 'heritage branding,' which is a marketing strategy that emphasizes a brand's long-standing history and values."[42]

Dr. Newman's expertise is vital to understanding the effect J&J's marketing practices had on consumers. Contrary to Defendants' assertions, it was not necessary for Dr. Newman to conduct new or additional research. J&J conducted its own research over decades to understand how its talcum powder products and the company were perceived by consumers. This research demonstrated that J&J's century of advertising led consumers to trust the company and its products, which J&J considered valuable.

Dr. Newman's qualifications and experiences support his ability to explain the subsequent effect J&J's marketing tactics had in distorting consumers' perceptions of the possible risks associated with its products and hist testimony will assist the jury.

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41 Han, Minju and George E. Newman (2022). The Curse of the Original: How and when heritage branding reduces consumer evaluations of enhanced products. *Journal of Consumer Psychology*, 32(1), 77-86.

42 Han (2022) (*citing* Hakala, Ulla, Sonja Lätti and Birgitta Sandberg (2011). "Operationalising Brand Heritage and Cultural Heritage." *Journal of Product and Brand Management*, 20(6), 447-56; Urde, Mats, Stephen A. Greyser and John M.T. Balmer (2007). "Corporate Brands with a Heritage." *Journal of Brand Management*, 15(1), 4-19.

LEGAL STANDARD

The PSC incorporates, as if set forth in entirety, the legal standards included in *The Plaintiffs' Steering Committee's Brief Regarding the Rule 702 Standard*, ECF No. 32994 ("Rule 702 Standard Brief"), as supplemented herein.

ARGUMENT

I. DRS. KESSLER, PLUNKETT, SAGE, AND NEWMAN OFFER APPROPRIATE EXPERT OPINIONS

A. Plaintiffs' Experts Provide Helpful Summaries of Information that Will Assist the Trier of Fact

Defendants contend that Plaintiffs' experts' testimony should be excluded because an expert cannot "simply rehash internal corporate documents," "simply parrot[s] [d]efendants's corporate documents," or "offer a narrative account of events from them."[43] Plaintiffs' experts' reports and testimony, however, do not "simply rehash" or "simply parrot" Defendants' internal corporate documents and do not merely "offer a narrative account of events from them."

A factual narrative may be admissible where, as here, the facts are voluminous and complex and narration would help a jury better understand them.[44]

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[43] Defs.' Mot. at 9-10 (citing *O'Bryant v. Johnson & Johnson*, No. 20-2361, 2022 WL 7670296, at *13 (D.N.J. Oct. 13, 2022)).

[44] *See*, *e.g.*, *Terry v. McNeil-PPC, Inc. (In re: Tylenol Acetaminophen Mktg.*, MDL No. 2436 2:13-md-0436, 2016 U.S. Dist. LEXIS 117594, at *27, 2016 WL 4538621 (E.D. Pa. Aug. 31, 2016) (emphasis added); *In re: Yasmin & YAZ (Drospirenone) Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011).

Under Fed. R. Civ. P. 26(a)(2), experts are required to summarize the facts and data considered in their expert reports.[45] Moreover, "[w]hether such evidence is adopted by the jury is not determined in [a] *Daubert* motion."[46] To the extent a defendant wishes to challenge the underlying factual basis for an expert's opinion, it may do so on cross-examination.[47]

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[45] *See also In re: Glumetza Antitrust Litig.*, No. C 19-05822 WHA, 2021 WL 3773621, at *20 (N.D. Cal. Aug. 25, 2021) (denying motion to exclude expert testimony "regarding plaintiffs' 'preferred view' of the factual narrative" and recognizing that "[i]t is common, indeed required, under Rule 26(a)(2), for an expert to summarize the facts and data considered in their report."); *In re: 3M Combat Arms Earplug Prod. Liab. Litig.*, No. 3:19MD2885, 2021 WL 765019, at *41 (N.D. Fla. Feb. 28, 2021) (finding experts' opinions were "not unhelpful narrative accounts but are instead commentary on evidence that explains the factual bases of their opinions"); *Scentsational Techs., LLC v. Pepsi, Inc.*, No. 13-CV-8645 (KBF), 2018 WL 1889763, at *4 (S.D.N.Y. Apr. 18, 2018), *aff'd* 773 F. App'x 607 (Fed. Cir. 2019) ("It is certainly the case that an expert may and often must rely on facts—and that the expert will state them in a report.").

[46] *Silipena v. Am. Pulverizer Co.*, Civ. Action No. 16-711, 2024 U.S. Dist. LEXIS 114238, at * 52, 2024 WL 3219226 (D.N.J. June 28, 2024).

[47] *Id.* (citing *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002)) (noting that "Rule 705, together with Rule 703, places the burden of exploring the facts and assumptions underlying the testimony of an expert witness on opposing counsel during cross-examination."). *See also Staub v. Breg, Inc.*, No. CV 10-02038-PHX-FJM, 2012 WL 1078335, at *3 (D. Ariz. Mar. 30, 2012) ("Objections to narrative testimony are best made at trial."); *In re Actos Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *10 (W.D. La. Jan. 10, 2014) ("The objection that testimony is 'narrative' is an objection as to form, foundation, or responsiveness, and must be presented at trial."); *In re Yasmin & YAZ Prods. Liab. Litig.*, MDL No. 2100, 2011 WL 6302287, at *8 (S.D. Ill. Dec. 16, 2011) (issues concerning narrative testimony should be "decided at trial in context specific situations"); *In re: 3M Combat Arms Earplug Prod. Liab. Litig.*, No. 3:19MD2885, 2021 WL 765019, at *41 (N.D. Fla. Feb. 28, 2021) ("The Court will not issue a 'blanket ban' on discussions of internal documents and declines to parse

In *In re: Juul Labs, Inc.*, the defendants argued that significant portions of the experts' testimony was "nothing more than impermissible and unhelpful 'narration' of the content of defendants' documents or depositions testimony, their views of the relevant regulatory schemes, and defendants' financial documents and sales information, all of which juror could understand on their own."[48] The court rejected this argument, finding that it would "not exclude expert testimony that helps explain the regulatory background that is relevant to this case or testimony regarding, for example, [the defendant]'s marketing and advertising campaigns."[49] The court continued, stating that the "experts appropriately reviewed thousands of pages of documents and extensive data sets and then offered condensed testimony regarding defendants' documents and sales information."[50]

Plaintiffs' experts appropriately reviewed thousands of pages of Defendants' internal documents and communications, sales and marketing analyses, regulatory and governmental data, peer-reviewed articles, and studies and reports on talc. As in *Juul*, Plaintiffs' experts offer testimony addressing Defendants' documents, and the marketing, sale, distribution, and impact of J&J's talcum powder products.

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the experts' reports and depositions for statements that may cross the line into improper factual narration.").

48 *See In re: Juul Labs, Inc. Mktg. Sales Pracs. & Prods. Liab. Litig.*, Case No. 19-md-02913-WHO, 2022 U.S. Dist. LEXIS 99163, at *104-5 (2022 WL 1814440) (N.D. Cal. June 2, 2022).

49 *See In re: Juul Labs, Inc.* U.S. Dist. LEXIS 99163, at *105.

50 *Id.*

1. Kessler

Defendants' argument that Dr. Kessler's testimony is an improper "factual narrative" is recycled from previous *Daubert* motions to exclude testimony from Dr. Kessler that other courts have found unpersuasive. Courts have routinely rejected this "factual narrative" objection because such an objection should be made *at trial*, not prior to Dr. Kessler taking the stand.[51]

Dr. Kessler references thousands of documents that offer the foundation for his opinions on the reasonableness of Defendants' actions given the regulatory scheme and industry standards.[52] Because these documents contain information unfamiliar to a layperson (*e.g.*, industry acronyms, description of industry and

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[51] *See King v. DePuy Orthopaedics, Inc.*, No. 23-00196, 2023 BL 307319, at *4 (D. Ariz. Aug. 31, 2023) ("objections to narrative testimony are best made at trial."); *In re: Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2017 BL 475991 (D. Ariz. Dec. 21, 2017) (rejecting defendants' arguments regarding narrative testimony and holding "Defendants may object at trial if Dr. Kessler begins simply regurgitating facts instead of using relevant facts to support for his expert opinions."); *Wells v. Allergan, Inc.*, Case Number CIV-12-973-C, 2013 BL 419394, at *3 (W.D. Okla. Feb. 4, 2013) ("To the extent the facts relied upon by Dr. Kessler in forming his opinions are relevant and not cumulative, Dr. Kessler may include them in his testimony . . . Defendant may object at trial if Dr. Kessler appears to be simply regurgitating facts, rather than using relevant facts as context for his expert opinions.")

[52] Dr. Kessler had access to the following: "1) MDL discovery repository; 2) deposition transcripts and exhibits; 3) trial testimony and exhibits; 4) all of the documents available on Johnson & Johnson's (JNJ) website Review the Evidence page of https://www.factsabouttalc.com; [and] FDA's website. Kessler Report at 3; *see also* Appendix C to Kessler Report, which is a 97 page list of the thousands of documents he reviewed in forming his opinions.

regulatory processes, etc.), Dr. Kessler's testimony will provide context to the documents and help the jury evaluate them in light of the claims in the case.

As a former Commissioner of the U.S. Food and Drug Administration and corporate consultant, Dr. Kessler has relied on the same type of information to perform his work. Over decades, Dr. Kessler's reliance on J&J documents as a foundation for his testimony as a scientist, regulatory expert, government official, researcher, and corporate consultant is entirely proper.

2. Plunkett

Dr. Plunkett appropriately relies on J&J documents to support her opinions on: (1) the toxic and carcinogenic properties of talcum powder products and how these products increase the risk of ovarian cancer; (2) the reasonableness of Defendants' actions given the regulatory scheme and industry standards; and (3) the necessity of a warning on the products given the knowledge of Defendants about the historical dangers of the products. Because these documents contain information unfamiliar to a layperson (*e.g.*, industry jargon and acronyms, description of industry and regulatory processes, etc.), Dr. Plunkett's explanation of

the documents will assist the jury in evaluating them in light of the claims in the case.[53]

As a toxicologist and regulatory consultant, Dr. Plunkett relies on this same type of information as part of her methodology underlying her professional opinions. Dr. Plunkett should be allowed to testify about documents that relate to her opinions and are within her expertise and discipline as a toxicology, pharmacology, and regulatory expert.

3. Sage

In forming his opinions in this case, Dr. Sage reviewed relevant laws and regulations, standards in the industry, peer-reviewed literature, publicly available information, and relevant corporate documents.[54] In his report, he provides summaries of documents he reviewed and considered in reaching his opinions. Given Dr. Sage's longstanding background in corporate and health law, his analysis of internal documents relevant to his expertise will provide the jury with background and prospective into the documents. The jurors will need context and background from experts who understand the regulatory and industry framework. Dr. Sage, as an academic and professor of law who studies and teaches regulatory

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53 *See* Fed. R. Evid. 702(a) ("scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or determine a fact in issue[.]").

54 Sage Report at 2.

practices and health law, is well-suited to assist the jurors.

4. Newman

Dr. Newman has reviewed thousands of pages of Defendants' internal documents, including decades of marketing materials, consumer studies, and consumer impact data, as well as studies and reports from outside sources. Courts have routinely permitted plaintiffs' marketing experts to provide a factual narrative relating to actions taken by defendants in marketing a product or developing a brand.[55]

Likewise, Dr. Newman's explanation of the actions (and inactions) of J&J is not simply a recitation of facts. Dr. Newman offers meaning to Defendants' actions and inactions and the purposes served in developing Defendants' brand.[56]

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[55] *See*, *e.g.*, *In re: Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prod. Liab. Litig.*, 2016 WL 807377, at *9 (E.D. Pa. Mar. 2, 2016, No. 2436) (marketing expert's "explanation of the actions undertaken by the defendants in creating the Tylenol brand is not simply a recitation of facts. He translates the meaning of those actions and what purpose they serve in branding.").

[56] *See* Newman Report, Summary of Opinion, ¶¶ 12-20; *see also id.*, Discussion, ¶¶ 21-99 (discussing, for example, Defendants' direct and indirect marketing strategies and efforts and costs of same; market research conducted by J&J; timing and extent of J&J's awareness of potential health risks; timing and extent of developing and testing a safe, cornstarch-based replacement; J&J's decisions relating to offering a cornstarch-based product alongside of its talc products; epidemiological studies conducted and their results; FDA and Cancer Prevention Coalition's actions related to talc-based products; and the eventual decision in 2022 to transition to an "all cornstarch-based baby powder portfolio").

Defendants mischaracterize Dr. Newman's opinion as a "lay" opinion that must be excluded.[57] By way of his expertise and experience, Dr. Newman can assist the jury by explaining J&J's marketing tactics and strategy used in distorting consumers' perceptions of the possible risks associated with its products.

B. Plaintiffs' Experts Provide Admissible Regulatory Opinions

1. Kessler

Dr. Kessler's opinions address the relevant regulatory standards Defendants were subject to, relevant industry standards, and the appropriateness of Defendants' actions given the information they possessed at the time. Dr. Kessler is not offering ultimate legal conclusions concerning Defendants' liability. Other courts have recognized this distinction with regards to Dr. Kessler's opinions and rejected arguments that Dr. Kessler's testimony regarding FDA regulations constitutes "improper legal opinions."[58]

Dr. Kessler's opinions will assist the jury in assessing the reasonableness of Defendants' actions and by educating the jury on industry standards and applicable

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[57] Defs.' Mot. at 13.

[58] *In re: Bard IVC Filters Prods. Liab. Litig.* 2017 WL 6523833, ("an expert witness may not opine on an ultimate issue of law . . . Dr. Kessler may, however, offer opinions concerning the FDA regulatory process and [defendant's] compliance with this process."); *Allergan, Inc.*, 2013 WL 7208221 at *1 ("Dr. Kessler may *not* testify as to the elements of a strict liability or negligence claim under Oklahoma law but *may* testify as to the law governing FDA regulations.") (emphasis in original); *In re: Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14-C 1748, 2017 WL 1836443, at *15 (N.D. Ill. May 8, 2017) ("[The]

regulatory schemes.[59] It will ultimately be up to the Court to explain to the jury the applicable law in the case on negligence, failure to warn, or other claims and up to the jury to decide whether Defendants should be held liable based on the Court's explanation of the law. Dr. Kessler's testimony is one of multiple pieces of evidence the jury can consider in their deliberations.

2. Sage

Like Dr. Kessler, Dr. Sage, a legal expert on health law and corporate responsibility, should be allowed to offer his opinions on industry standards and the regulatory framework and whether Defendants complied with these standards in the marketing and sale of talcum powder products.[60] And, like Dr. Kessler, Dr. Sage is not offering ultimate legal conclusions about Defendants' liability. Rather, he explains the industry standards and regulatory framework through the lens of Defendants' actions throughout the years while they sold Talcum Powder Products.

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plaintiffs' claims are based on state law doctrines such as negligence, failure to warn, strict products liability, breach of warranty, and fraud. The ultimate conclusions a jury will have to draw are rooted in state law, not federal law. And Dr. Kessler's testimony does not cover the ultimate issues that the jury will decide; rather, it concerns . . . FDA regulations. This is neither irrelevant [nor] improper[.]").

[59] Dr Kessler's "opinions in this case focus on the responsibilities of cosmetic manufacturers, focusing on the regulatory interface between cosmetic manufacturers and the FDA, as well as industry standards." Kessler Report at 5.

[60] *See* Sage Report at 28-29 for a summary of his opinions related to industry standards and applicable regulatory framework.

His testimony will provide jurors with valuable insight into the cosmetic regulatory system.

3. Plunkett

Dr. Plunkett relied on her significant experience advising industry on FDA-regulation and the application of relevant regulatory standards. Her opinions do not interpret statutes and regulations as a lawyer, but as a scientist. Dr. Plunkett reviewed 21 C.F.R. § 740.1, which states "[t]he label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product."[61] Dr. Plunkett offers a scientific opinion, not a legal opinion. Dr. Plunkett asks whether talc was a "health hazard that may be associated with the product."[62] Her opinion in response to that question is based on science. As a toxicologist, Dr. Plunkett concludes that talc was a health hazard and, because of this, Defendants were required to place a warning in compliance with the regulation.

Dr. Plunkett has "advised [] clients on regulatory issues and strategies for their products . . . [including] on issues related to statements regarding efficacy and warnings for their products based on the current labeling regulations [.]"[63] Dr.

61 21 C.F.R. § 740.1.
62 *Id.*
63 Plunkett Report at ¶6.

Plunkett has been described by one court as an "FDA regulatory specialist."[64] As Defendants are aware, Dr. Plunkett has been qualified to give labeling opinions on its two non-prescription, over-the-counter pain products, Tylenol and Motrin. In *Tylenol*, the Court rejected J&J's challenge to her labeling and regulatory opinions: "Dr. Plunkett's testimony about the Tylenol label are made in reference to her opinions as a regulatory expert - about what actions she believes the Defendants should have taken to fulfill their legal duties as a drug manufacturer. She is qualified to offer such as opinion."[65] In the Motrin case, the Court held that "Dr. Plunkett is qualified and has a reliable foundation for her opinions concerning the OTC status and labeling of Motrin products."[66] Further, the MDL court in *Xarelto* held that Dr. Plunkett was qualified to testify as to all "regulatory matters, including label content."[67] Here, Dr. Plunkett is similarly qualified to offer testimony about the FDA regulations and labeling requirements.

Dr. Plunkett's regulatory and labeling opinions do not "impermissibly usurp the role of the Court and the jury."[68] Rather, her opinions are offered to assist the jury and explain the applicability of FDA regulations to the cosmetic industry and

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64 *In re: Zyprexa Prods. Liab. Litig*., 253 F.R.D. 69, 179 (E.D.N.Y. 2008).

65 *In re: Tylenol*, 2016 WL 4039329 at *7.

66 *Newman by and through v McNeil Consumer Healthcare,* 2013 WL 9936293, at *5 (N.D. Ill. Mar. 29, 2013).

67 *In re: Xarelto*, 2017 U.S. Dist. LEXIS at *4.

68 Defs.' Mot. at 42.

whether defendants met those requirements. As such, the Court will retain its responsibility to instruct the jury on the law as to the claims raised by Plaintiff, and the jury will retain its responsibility to determine whether Defendants are liable for failure to comply with industry standards and applicable regulatory requirements.

Courts have repeatedly allowed Dr. Plunkett to testify to FDA requirements for multiple prescription and non-prescription products subject to FDA oversight using her sound methodology.[69] These rulings permitted Dr. Plunkett to testify on both regulatory and labeling issues. The findings are summarized by the court in *In Re: Tylenol*, which concluded that she could testify to the label using her methodology opinions as "a regulatory expert about what actions Dr. Plunkett believes Defendants should have taken to fulfill their legal duties as a drug manufacturer."[70]

Dr. Plunkett is an expert in FDA regulations. She should be allowed to testify to the applicability of the FDA regulations within the regulatory framework of a cosmetic manufacturer and the appropriate industry standards resulting from that regulatory framework.

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69 *See In re: Tylenol*, 2016 WL 4039329 at *7; *In re: Seroquel*, 2009 WL 3806435, at *11-12; *In re: Gadolinium*, 2010 WL 1796334, at *17; *In re: Xarelto Rivaroxaban Prods. Liab. Litig.*, No. 2592, 2017 U.S. Dist. LEXIS 56628, at *3-4 (E.D. La. April 12, 2017).

70 *In re: Tylenol*, 2016 WL 4039329, at *7.

C. Plaintiffs' Experts Opinions Based on Defendants Own Internal Communications Are Admissible Expert Evidence

Plaintiffs' experts offer opinions based on their review of Defendants' documents, statements and actions, studies, reports, data and deposition testimony. They do not offer personal, subjective opinions relating to J&J's state of mind or its culpability.

The Third Circuit has determined that the admissibility of expert testimony relating to a defendant's "state of mind" "will depend on the context in which it is made, the purpose for which it is offered, and the foundation that has been laid for it."[71] For example, in a case involving alleged infringement of a trademark in the form of back pocket stitching design on denim, the defendant sought to exclude the testimony of the plaintiff's expert who was proffered as an expert in the use of a logo as a visible brand symbol that had acquired commercial strength through use, promotion, and sales.[72] The defendant contended the plaintiff's expert was not qualified to testify on the defendant's state of mind.[73] The plaintiff countered, arguing the expert was not opining as to the defendant's subjective intent, but

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[71] *See SEC v. Ambassador Advisors, LLC*, Civil No. 5:20-cv-02274-JMG, 2022 U.S. Dist. LEXIS 110354, at *3, 2022 WL 2188145 (E.D. Pa. Feb. 28, 2022) (citing Fed. R. Evid. 703)) (recognizing that the court "cannot meaningfully address these objections until they have been sharpened by the context of trial.").

[72] *See Am. Eagle Outfitters, Inc. v. Walmart, Inc.*, 2:20-CV-00412-MJH, 2023 U.S. Dist. LEXIS 21641 (W.D. Pa. Feb. 6, 2023).

[73] *Id.* at *9.

rather, the expert's opinions were based upon her experience and interaction with the defendant's executives.[74] The court permitted the expert's opinion relating to the defendant's "intent" and state of mind, finding her opinion was supported by the cumulative evidence that she analyzed, including testimony, and her interactions with the defendant's executives.[75] The court further determined that the expert was qualified to educate the jury on the logo's "significance to a brand's development, design, and marketing" to assist the jury to reach its conclusion about the defendant's "state of mind in its development" of the logo.[76]

Courts have also permitted and found it "entirely appropriate" for plaintiffs' experts to offer evidence that "could allow a jury to infer what the defendants' corporate state of mind would be."[77] This Court has also determined that excluding expert testimony concerning certain topics, including the defendant's "alleged motives or state of mind," is not proper for a *Daubert* motion.[78]

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74 *Id.* at *9.

75 *Id.* at *10.

76 *Id.* at *10.

77 *In re: Tylenol (Acetaminophen) Marketing, Sales Prac. and Prod. Liab. Litig.*, 181 F. Supp. 3d 278, 296 (E.D. Pa. 2016).

78 *See*, *e.g.*, *Glynn v. Merck Sharp & Dohme Corp. (In re: Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, Civil Action No. 11-5304, 08-08, 2013 U.S. Dist. LEXIS 51552, at *32, 2013 WL 1558690, at *10 (D.N.J. Apr. 10, 2013) ("[B]ecause *Daubert* concerns the narrow issue of whether expert testimony is admissible, this is not the appropriate time for Defendant to request that the Court preclude [plaintiff's expert] from testifying about certain topics. Defendant may question [the expert's] opinions or methodology on cross-examination.").

As in *American Eagle*, Plaintiffs' experts base their opinions on their experience and the cumulative evidence they have analyzed, including Defendants' own internal and external documents, statements, and actions and inactions.

1. Kessler

Dr. Kessler's opinion addresses what Defendants had *notice* of based on his review of the factual record, including internal company documents and testimony from Defendants' corporate representatives.[79] Dr. Kessler's opinions evaluate the Defendants' conduct and the reasonableness of Defendants' conduct in light of regulatory requirements and industry standards, including whether they were compliant with FDA regulations. Dr. Kessler will not offer speculative testimony regarding Defendants' state of mind or motive.[80]

In *In re: Tylenol*, the U.S. District Court for the Eastern District of Pennsylvania rejected a similar argument that an FDA expert cannot opine on what a Defendant knew or should have known based on the information it had in its possession:

> [The expert] states what the defendants knew about risks of acetaminophen-induced liver failure based on internal documents or depositions by defense witnesses she reviewed. Her opinions are not based on speculation or inference. She offers these opinions to show

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79 *See DePuy Orthopaedics Inc.*, 2023 BL 307319, at *5 (rejecting similar argument and holding "Dr. Kessler's testimony relates to opinions about when Defendants had notice of the risks, not their state of mind . . . Therefore, this testimony will be allowed subject to objections at trial.").

80 *See* Kessler Dep. at 312-313

> how the defendants' actions differed from what a reasonable drug manufacturer should or would have done. In context, her statements about what the defendants knew or did not know would be appropriate. These opinions will help the jury understand how the defendants' actions may have fallen short of the duties required of them.[81]

Dr. Kessler, and any qualified witness for that matter, can rely on company documents to demonstrate what the defendants *knew or should have known* at a given time, especially where this information is directly related to his opinions.

2. Plunkett

Dr. Plunkett is not testifying regarding the intent of J&J. Rather, she will testify as to what the evidence shows at various relevant points in history.[82]

As with many of Defendants' other arguments, their "state of mind" argument is recycled from other cases where courts have specifically rejected it. Again, Defendants' previous attack on Dr. Plunkett, and the court's rejection of that argument, is dispositive:

> [Dr. Plunkett] states what the defendants knew about risks of acetaminophen-induced liver failure based on internal documents or depositions by defense witnesses she reviewed. Her opinions are not based on speculation or inference. She offers these opinions to show how the defendants' actions differed from what a reasonable drug manufacturer should or would have done. In context, her statements about what the defendants knew or did not know would be appropriate. These opinions will help the

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81 *In re: Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prod. Liab. Litig.*, No. 2:12-CV-07263, 2016 WL 4039329, at *6 (E.D. Pa. July 28, 2016).

82 Plunkett 2023 Dep. 155:5-10.

> jury understand how the defendants' actions may have fallen short of the duties required of them.[83]

Here, Dr. Plunkett has performed the same type of analysis. Her opinions are based in part on a review of internal company documents. For example, as it relates to her failure to warn opinion, Dr. Plunkett states as follows:

> In order to add warnings to a product label in the United States, the company must be aware of the risk, which is why I have outlined what was known and when it was known (discussed above in detail). A review of internal company documents, documents from Johnson & Johnson, Imerys, and the PCPC show that talc ingredient manufacturers and the manufacturers of talcum powder products were following the published literature and were also intimately involved in the safety assessments of talc over the years. Thus, the defendants were at least aware for decades that ovarian cancer may be associated with the use of talcum powder products.[84]

Dr. Plunkett can rely on company documents to demonstrate what the defendants knew or should have known at a given time.

3. Sage

Similar to Dr. Plunkett, Dr. Sage has explicitly stated he is not offering any opinions on intent. The following exchange from his deposition makes that clear:

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[83] *In re: Tylenol*, 2016 WL 4039329 at *6. Dr. Plunkett was also approved to testify on this issue in the Xarelto MDL. *In re: Xarelto*, 2017 U.S. Dist. LEXIS at *4.

[84] Plunkett Report at ¶109.

> Q. Do you intend to testify about the intent of Johnson & Johnson in regards to any document and, in particular, the Facts About Talc website?
>
> A. No.
>
> Q. Do you intend to talk about the motives of anyone at Johnson & Johnson as it relates to talcum powder products?
>
> A. No.
>
> Q. Do you intend to testify that Johnson & Johnson in setting up the Facts About Talc website did so to lie to the public about the safety of talc?
>
> A. I am a student of institutions both governmental and corporate in these regulatory contexts. I am extremely interested in how a company as large and as experienced and as accomplished as Johnson & Johnson has been in many domains could, in my opinion, fall so far short of its obligations in this respect. So would I offer a conclusion about corporate motivation? No.[85]

As with Plaintiffs' other experts, Dr. Sage offers testimony about the information Defendants possessed at certain points in time, how Defendants acted and communicated internally and externally, and whether those practices were reasonable under the circumstances.

4. Newman

Dr. Newman is not offering improper "state of mind" testimony. He bases his opinions on information Defendants possessed at certain points in time, how

[85] Sage Dep. at 313:13-314:10

Defendants acted and communicated internally and externally, and whether those practices were reasonable under the circumstances.[86]

Courts have routinely permitted marketing and advertising experts to offer opinions based on a review of the defendant's internal corporate documents and analysis of its marketing practices. For example, in *In re: DePuy*, the court found that Dr. Drumright, who was offered as a marketing and advertising expert, had sufficient expertise based on her education and experience to qualify as an expert, and that her opinions about marketing of the defendant's hip implant device were within her areas of expertise.[87]

The *DePuy* court found that the marketing and advertising expert testimony was "helpful to the factfinder" and that the expert "applied her specialized knowledge in the discipline of marketing, including the areas of marketing codes, regulations, and guidelines, to analyze the voluminous specific marketing representations made by Defendants[.]"[88]

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86 *See* Newman Report at ¶¶12-99.

87 *In re: DePuy Orthopaedics, Inc.*, MDL Dkt. No. 3:11-MD-2244-K, 2016 U.S. Dist. LEXIS 194777, at *28 (N.D. Tex. Oct. 3, 2016) (2016 WL 9560133).

88 *In re: DePuy Orthopaedics, Inc.*, MDL Dkt. No. 3:11-MD-2244-K, 2016 U.S. Dist. LEXIS 194777, at *28 (N.D. Tex. Oct. 3, 2016) (2016 WL 9560133). "Dr. Drumwright offers opinions from the application of her expertise to documents and their contents, not speculation as to [defendant]'s state of mind." *In re: DePuy Orthopaedics, Inc.*, MDL Dkt. No. 3:11-MD-2244-K, 2016 U.S. Dist. LEXIS 194777, at *28 (N.D. Tex. Oct. 3, 2016) (2016 WL 9560133).

Furthermore, the court found that "any alleged speculation within [the expert]'s report is not properly the subject of this *Daubert* analysis and should be addressed to the Court in the context of the presentation of evidence at trial."[89]

Similarly, the court in *In re: Juul Labs* determined that plaintiffs' expert opinions concerning the defendants' corporate knowledge and intent in developing and marketing its vaping product, as well as its apparent knowledge of and reactions to the problem of youth consumption, was likely relevant and admissible, citing a basis in the record for the experts to testify from their review of defendants' documents or deposition testimony.[90]

In *In re: Juul*, the defendant also argued that expert testimony concerning what the defendant knew and intended regarding its marketing and product design was impermissible intent and state of mind evidence. The court rejected this argument as well and determined that the argument went to the weight of the testimony and was appropriate for cross examination, not exclusion.[91]

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89 *In re: DePuy Orthopaedics, Inc.*, MDL Dkt. No. 3:11-MD-2244-K, 2016 U.S. Dist. LEXIS 194777, at *29 (N.D. Tex. Oct. 3, 2016) (2016 WL 9560133) (citing *In re: Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 09-02100, 2011 U.S. Dist. LEXIS 145593, 2011 WL 6302287, at *8 (E.D. Ill. Dec. 16, 2011) (Herndon, C.J)).

90 *See In re: Juul Labs, Inc. Mktg. Sales Pracs. & Prods. Liab. Litig.*, Case No. 19-md-02913-WHO, 2022 U.S. Dist. LEXIS 99163, at *105-06 (2022 WL 1814440) (N.D. Cal. June 2, 2022).

91 *In re: Juul*, 2022 U.S. Dist. LEXIS 99163, at *119, 120-21.

Here, as in *In re: DePuy* and *In re: Juul Labs*, Dr. Newman reviewed thousands of corporate internal documents. His review included but was not limited to decades' worth of J&J's marketing and sales materials, Defendants' internal and external communications, internal and external studies, reports, and memoranda. Dr. Newman's purpose in reviewing these materials was to determine what J&J promised to its consumers, what J&J stated its motivations were, and what J&J was aware of and when.[92]

In short, Dr. Newman's opinions address the messaging from the documents and their contents, not speculation as to Defendants' state of mind.

D. Plaintiffs' Expert Opinions Regarding Defendants' Corporate Responsibilities to Consumers Are Permissible

Plaintiffs' expert opinions relating to J&J's corporate responsibilities are not based on "personal, subjective views." Instead, these opinions are based on applicable industry standards, Plaintiffs' experts' background and experience, and J&J's own internal documents.

Similar to the arguments raised by J&J here, in *In re: DePuy*, J&J attempted to exclude plaintiffs' experts, arguing that any opinion offered by plaintiffs' experts

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[92] *See* Newman Report at ¶¶ 12-99; *see also* Appendix 1 to Newman Report (setting forth a timeline of studies and reports juxtaposed against Defendants' advertising messaging and efforts); Appendix 2 to Newman Report, A2-A through A2-X (J&J advertising relating to talc products and J&J's messaging regarding the safety of talc); Ex. A to Newman Report (Curriculum Vitae and References cited in Report).

regarding "ethical standards," including J&J's corporate credo and company ethics policies, were irrelevant, as they have no bearing on Defendants' compliance with the legal standards at issue in this case. The *DePuy* court rejected J&J's argument, noting that "opinions on ethical standards may be helpful to a jury when ethical obligations are of consequence to the issues to be decided by the jury, such as an attorney's ethical obligations in a breach of fiduciary duty claim or a physician's standard of care in claims of negligence."[93]

J&J argues ethical opinions are irrelevant in matters of product liability and marketing claims. The *DePuy* court rejected this same argument, holding that "expert testimony regarding applicable ethical standards may be helpful in cases where, as here, one party's duties to another are in question through, for example, negligence claims, or if the standard of care of alleged negligence is not within the ordinary experience of lay persons."[94] The court continued, finding that "testimony

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93 *In re: DePuy Orthopaedics, Inc.*, MDL Dkt. No. 3:11-MD-2244-K, 2016 U.S. Dist. LEXIS 194777, at *29 (N.D. Tex. Oct. 3, 2016) (2016 WL 9560133)." "The ethical issues here include published industry standards, which are valid sources when looking to the applicable standard of care." *In re DePuy Orthopaedics, Inc.*, MDL Dkt. No. 3:11-MD-2244-K, 2016 U.S. Dist. LEXIS 194777, at *29-30 (N.D. Tex. Oct. 3, 2016) (2016 WL 9560133) (citing *Frazier v. Cont'l Oil Co.*, 568 F.2d 378, 381-83 (5th Cir. 1978)).

94 *In re: DePuy Orthopaedics, Inc.*, MDL Dkt. No. 3:11-MD-2244-K, 2016 U.S. Dist. LEXIS 194777, at *30 (N.D. Tex. Oct. 3, 2016) (collecting cases).

on compliance with industry standards and Defendants' own internal policies, therefore, is sufficiently relevant and helpful to the jury to be admitted."[95]

Similarly, in *In re: Juul Labs*, the defendants moved to exclude expert comparison of acts of the defendants against industry or regulatory "standards of conduct," arguing that the industry standard testimony violates Rule 702 as unhelpful and not based on actual expertise of many experts.[96] The court found that plaintiffs' expert opinions concerning the comparison of defendants' acts to industry standards of conduct is likely relevant and admissible, again citing a basis in the record for the experts to testify from their review of defendants' documents or deposition testimony.[97] Furthermore, experts are allowed to testify about industry standards even where the testimony relies in part on the expert's understanding of the requirements of law.[98]

Here, Plaintiffs' experts offer opinions relating to how Defendants violated industry standards and Defendants' own internal policies.

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95 *In re: DePuy Orthopaedics, Inc.*, MDL Dkt. No. 3:11-MD-2244-K, 2016 U.S. Dist. LEXIS 194777, at *30 (N.D. Tex. Oct. 3, 2016).

96 *See In re: Juul Labs, Inc. Mktg. Sales Pracs. & Prods. Liab. Litig.*, 2022 U.S. Dist. LEXIS 99163, at *105 (2022 WL 1814440) (N.D. Cal. June 2, 2022).

97 *See In re: Juul Labs, Inc. Mktg. Sales Pracs. & Prods. Liab. Litig.*, 2022 U.S. Dist. LEXIS 99163, at *106 (2022 WL 1814440) (N.D. Cal. June 2, 2022).

98 *In re: Juul Labs, Inc. Mktg. Sales Pracs. & Prods. Liab. Litig.*, 2022 U.S. Dist. LEXIS 99163, at *106-07 (2022 WL 1814440) (N.D. Cal. June 2, 2022) (collecting cases).

1. Kessler

Defendants attempt to redefine Dr. Kessler's testimony, contending he is "offering subjective testimony considering the ethical appropriateness of the J&J Defendants' actions."[99] Dr. Kessler is not opining as to the subjective ethicality of Defendants' actions. He is offering opinions as to the reasonableness and appropriateness of Defendants' conduct in light of the relevant, objective regulatory requirements and industry standards.

Dr. Kessler reviewed documents produced in the talc MDL, trial testimony and exhibits, including testimony from Johnson & Johnson's corporate representatives, documents available on Johnson & Johnson's website pertaining to talc litigation (http://www.factsabouttalc.com), and documents from the FDA, including applicable legislation and regulations.[100] Dr. Kessler also performed reviews of the epidemiology, laboratory testing methodology, chemical and geological relationship between talc and asbestos, health consequences with asbestos and elongated mineral particles, and product formulation and manufacturing.[101] Dr. Kessler reviewed all of this in light of his extensive experience in the regulatory sphere. The methodology used by Dr. Kessler was consistent with that used to address regulatory questions in academia, his work as a

99 Defs.' Mot. at 21.
100 *See* Kessler Amended Report at 3.
101 *Id.* at 5-6.

government official, and as a board member advising corporate entities for over forty years.[102]

Once again, Defendants' argument is one that has been rejected elsewhere:

> Dr. Kessler's opinions are tied to his experience, including as chairman of the compliance committee of a medical device company and as head of the FDA which regulated, among other things, medical devices. The Court agrees that he has the background to testify about ethical standards for medical device companies and the testimony is helpful to a jury in understanding the relevant standard of care.[103]

As recognized in *DePuy*, Dr. Kessler has the experience necessary to offer opinions on ethical standards in the cosmetic industry that would be applicable to Defendants.

2. Plunkett

Dr. Plunkett's opinion about whether Defendants acted reasonably in the face of mounting evidence of the risk of talc-induced ovarian cancer, *i.e.*, whether they acted as "reasonable companies" under the circumstances-is based on among other things, the FDCA and regulations of the FDA relating to the development and marketing of cosmetic ingredients and finished cosmetic products, as well as documents produced during the litigation (internal company documents, depositions of company employees, expert reports of other experts in the litigation,

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102 *Id.* at 3.

103 *DePuy Orthopaedics Inc.*, 2023 BL 307319, at *4.

or documents found on public sites).[104] Given her experience with FDA regulated products, including cosmetics, she analyzed that information and described the basis of her opinions based upon the weight-of-the-evidence indicating how Defendants responded to the talc-induced ovarian cancer risk in a way that was unreasonable and failed to comport with industry practice.[105]

Indeed, the United States Supreme Court has itself observed that not every expertise has a mathematical methodology that the defendants would seemingly impose.[106] The fact that there is no scientific "formula" applicable to Dr. Plunkett's industry practice opinions on what a responsible talc manufacturer "should or should not do" when faced with a deadly risk in a cosmetic product does not render her opinion unreliable. To the contrary, Dr. Plunkett's review of the applicable FDA regulations against the backdrop of her own extensive industry experience, her knowledge and expertise related to consumer product safety assessment, and her review of the record in this case is sufficient. As the court in *Tylenol* held, "[t]hese methods are an acceptable way to offer an opinion about industry standards."[107]

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104 Plunkett Report at ¶ 10.

105 *Id.* at ¶¶ 104-119.

106 *See e.g., Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 17, 150 (1999) ("There are many different kinds of experts and many different kinds of expertise.").

107 Id. at *7.

Second, Dr. Plunkett did not simply review and parrot information from a few documents, as Defendants insinuate. To the contrary, Dr. Plunkett "had access to a large database of internal company documents, documents produced as part of the discovery process in the litigation, and [she has] performed [her] own searches of this database" or "directed others to perform searches on my behalf."[108] Dr. Plunkett's report contains references to thousands of documents from this database of company documents.[109]

Dr. Plunkett's review of thousands of documents related to J&J, Imerys, and PCPC informed her opinions regarding talc and human health risks and safety assessment. Dr. Plunkett's testimony is appropriate for trial and the jury is entitled to hear her opinions.

3. Sage

Dr. Sage's opinions concerning Defendants' conduct are based on his extensive experience in corporate ethics[110] and were formed using a reliable methodology. Dr. Sage does not specifically opine on whether Defendants acting ethically (i.e. right or wrong). Rather, Dr. Sage opines that Defendants did not follow industry, regulatory, and internal guidelines (many of which Defendants

108 Plunkett Report at ¶10.

109 *Id.* at Appendix C.

110 As discussed earlier, Dr. Sage is an elected fellow of the Hastings Center on Bioethics, teaches professional ethics, and has published extensively in the area.

created themselves or had a hand in the creating) in addressing the health concerns related to Talcum Powder Products.

In their Motion, Defendants attempt to convert out-of-context comments Dr. Sage made in response to questions at his deposition into opinions about "how [he] felt" about Defendants' actions.[111] But Dr. Sage does not make these sort of statements in his report (the words "shock" or "disappointment" do not appear anywhere in the report), and Plaintiffs do not intend to elicit this sort of testimony from Dr. Sage at trial. Dr. Sage only made these comments in response to questioning by Defendants' attorneys.

4. Newman

Dr. Newman's opinions focus on J&J's marketing of their Talcum Powder Products. The practice of marketing is inherently "self-regulating through the various industry associations that set desired standards for the behavior of their members."[112] Marketing and advertising codes of conduct are determined by established codes promulgated by the major professional organizations in

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111 Defs.' Mot. at 23 (Dr. Sage testified that he found J&J's statements on "Facts About Talc" to be "disappointing, frankly shocking" and that J&J's failure to disclose risks was "very disturbing" and left him "really shocked." Dr. Kessler opines that J&J's claims that its product was "asbestos free" without sufficiently "vigorous efforts to improve" testing was "concerning." Such subjective statements are also not rooted in any reliable principle or methodology.).

112 *See Marketing Ethics & Society*, at p. 12, Dahl Stephan, and Lynne Eagle (2015).

marketing, such as the American Marketing Association,[113] the Association of National Advertisers,[114] and the American Advertising Federation (founded in 1905, among the oldest and largest marketing associations in the world).[115] The Federal Trade Commission also includes a Statement of Code of Conduct, which provides that member companies shall not engage in any deceptive, false, or unethical conduct, and shall ensure that no statements, promises, or testimonials are made that are likely to mislead consumers.[116]

Dr. Newman's expertise speaks directly to the nature of these widely held industry standards and codes of conduct, and he employed them in reaching his conclusions in this case. Further, as an educator, Dr. Newman has over fifteen

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113 *See* AMA Code of Ethics: https://www.ama.org/ama-statement-of-ethics, last visited on Aug. 19, 2024 (listing code of ethical conduct for marketers, including core values such as honesty, responsibility, equity, transparency, and citizenship).

114 *See* ANA Code of Ethics: https://www.ana.net/content/show/id/accountability-chan-ethicscode-final#bookmark11, last visited on Aug. 19, 2024.

115 *See* AAF's "The Advertising Principles of American Business," available at https://www.aaf.org/common/Uploaded%20files/Club%20Resources/CLB_Resources_Advertising_Principles.pdf, last visited on Aug. 19, 2024 (listing the number 1 principle, "Truth: Advertising **shall tell the truth**, and **shall reveal significant facts, the omission of which would mislead the public**.") (emphasis added).

116 *See* FTC's Statement of Code of Conduct, available at, https://www.ftc.gov/sites/default/files/documents/public_events/enforceable-codes-conduct-protecting-consumers-across-borders/direct-selling-association-code.pdf, last visited on Aug. 19, 2024.

years of experience in communicating these standards to current and future practitioners of marketing and will be a valuable asset to this Court and the factfinder in explaining how J&J's marketing practices impacted consumers.

II. DR. NEWMAN'S MARKETING OPINIONS AND DRS. PLUNKETT AND SAGE'S CLAIMS ABOUT THE SAFETY OF TALC ARE BASED ON RELIABLE METHODOLOGIES

A. Dr. Newman's Marketing Opinions Are Reliable and He Employed a Sound, Widely Recognized Scientific Methodology to Reach His Conclusions

Defendants admit Dr. Newman "rel[ies] on J&J's internal market research to demonstrate that J&J successfully cultivated trust with its consumers," yet argue that Dr. Newman "has no empirical data" that demonstrates that such trust affected consumers' perceptions of the safety of talc.[117] Plaintiffs offer Dr. Newman as an expert on marketing, advertising, and consumer psychology. Dr. Newman properly relied on Defendants' own internal documents, internal and external communications, internal marketing studies, internal and external data, reports, and studies, and he compared Defendants' marketing and advertising practices to well-known industry codes of conduct, as described above, *see supra*, I.D.4., utilizing a widely recognized scientific method to reach his conclusions. Dr. Newman began with a null hypothesis, *i.e.*, that Defendants' marketing and advertising practices

[117] Defs.' Mot. at 27.

were in line with the codes of conduct promulgated by well-recognized and established marketing organizations (AMA, ANA, FTC, etc.).

In his Expert Report, he explains the methodology he employed is "the same objectivity and systematic analysis I apply in my professional and academic career. I reviewed documents I requested of counsel relevant to the promotion and sale of Johnson's Baby Powder (hereafter JBP) and Shower to Shower (STS)."[118] Such documents included marketing materials and communications that were directed towards consumers, corporate documents discussing these products, testimony from J&J's former employees, publicly available information (e.g., newspapers and magazine articles), and the peer-reviewed scientific literatures relevant to talcum powder use.[119] In reviewing these documents, Dr. Newman explains that he sought to address six areas of inquiry: relevance, messaging, strategy, impact, product risks, and response.[120] He further explained that, in reaching his opinions, he considered "the totality of evidence" "in light of scientifically validated principles and theories from the literatures on psychology, consumer behavior, and behavioral economics . . . ."[121]

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118 Newman Report at ¶ 10.
119 *Id.*
120 *Id.*
121 *Id.* at ¶ 11.

Dr. Newman opines that the standard of care in marketing and advertising requires that companies provide accurate, reliable, and non-misleading information about their products, safety, and usage. Defendants' advertising and marketing excluded information known to Defendants about the potential dangers of their talc products, and the presence of a safer alternative product (cornstarch-based powder) that was desirable to consumers and that had been tested by Defendants. Dr. Newman explains how Defendants engaged in a series of integrated marketing strategies, including direct marketing and advertising to consumers that targeted certain demographics of consumers, public relations campaigns, and other marketing tactics, such as building on the "sacred bond of mother and child" in order the build the Johnson & Johnson brand or "Trustmark" through its "Golden Egg" to build its brand.

Courts routinely permit marketing experts to base their opinions on their experience and review of defendants' own internal documents.[122]

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[122] *See In re: Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 2016 WL 807377, at *1, 6 (E.D. Pa., Mar. 2, 2016, No. 2436) (allowing expert's opinion about marketing campaign based on his experience, and review of images from the campaign, internal documents and company depositions and recognizing that "[a] marketing professional's review and analysis of company documents to extrapolate marketing strategies, coupled with the expert's experience and background may be enough to establish that the expert's methodology is reliable"); Fed. R. Evid. 703 ("An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed."). *See also Krommenhock v. Post Foods, LLC*, 334 F.R.D. 552, 580 (N.D. Cal. 2020); *Post Foods*, 334 F.R.D. at 580 (allowing expert's opinions about

In a case involving alleged infringement of a trademark in the form of back pocket stitching design on denim, the defendant sought to exclude the testimony of the plaintiff's expert who was proffered as an expert in the use of a logo as a visible brand symbol that had acquired commercial strength through use, promotion, and sales.[123] The defendant raised many of the arguments raised by Defendants here, which were all rejected by a district court within the Third Circuit.[124]

The defendant in *American Eagle* argued that the expert's opinions should be excluded because they allegedly were not the product of reliable principles and methods and failed to conduct her own "independent study."[125] The court disagreed, recognizing that measuring "expert reliability" will depend on the type of expert being offered.[126] "In terms of expert reliability, the Supreme Court has held, 'there are many different kinds of experts, and many different kinds of

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marketing campaign based on his many years of marketing experience and his review of Kellogg's own internal consumer research and other documents"); *Golden W. Trading, Inc. v. BelGioioso Cheese, Inc.*, No. CV097803GHKAGRX, 2012 WL 12953447, at *1 (C.D. Cal. Apr. 16, 2012) (quoting *United States v. Simmons*, 470 F.3d 1115, 1123 (5th Cir. 2006)); *In re: Juul Labs., Inc. Mktg., Sales Pracs. & Prods. Liab. Litig.*, 2022 WL 1814440, at *4 (N.D. Cal. June 2, 2022) (finding marketing experts' methodologies sufficient based on their experience, review of relevant literature, and review of the record).

123 *See Am. Eagle Outfitters, Inc. v. Walmart, Inc.*, 2:20-CV-00412-MJH, 2023 U.S. Dist. LEXIS 21641 (W.D. Pa. Feb. 6, 2023).

124 *See id.*

125 *Id.* at *7.

126 *Id.* at *8.

expertise.'"[127] Accordingly, the *American Eagle* court determined that the expert's opinion on the strength of the logo at issue did not require any particular methodology, thus, the expert's opinion was more properly assessed upon her personal and professional experience and knowledge of designs and their significance, as well as the impact that the logo can have on the consumer.[128]

Additionally, in a case involving the marketing of a vaporized tobacco product, the defendant similarly argued that the plaintiffs' marketing experts must be excluded "because each failed to conduct any original empirical research about actual consumer perceptions of the defendant's marketing: how it impacted youth specifically or consumers more generally."[129] The defendant also argued that none of the experts empirically tested whether the defendant's "marketing and advertising conveyed specific health claims to youth or general consumers" or

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[127] *Id.* at *8 (quoting *Kumho Tire,* 526 U.S. at 150 (1999)). "'"[I]n cases not involving scientific testimony, "[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."'" *Id.* (quoting *Betterbox Communs., Ltd. v. BB Techs., Inc.*, 300 F.3d 325, 329 (3d Cir. 2002) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999))). "'In such cases. . . "the relevant reliability concerns may focus upon personal knowledge or experience."'" *Id.* (quoting *Betterbox*, 300 F.3d at 329) (quoting *Kumho Tire*, 526 U.S. at 150).

[128] *Id.* at *8.

[129] *See In re: Juul Labs, Inc. Mktg. Sales Pracs. & Prods. Liab. Litig.*, Case No. 19-md-02913-WHO, 2022 U.S. Dist. LEXIS 99163, at *73 (2022 WL 1814440) (N.D. Cal. June 2, 2022).

whether the defendant sufficiently conveyed health warnings about the product.[130] The court rejected these arguments, finding that the defendant failed to demonstrate that any particular claims within the MDL require specific types of empirical evidence to admit the experts' opinions regarding the impact of the defendant's marketing.[131]

Here, as in *In re: Juul Labs*, Defendants have failed to demonstrate that the particular claims within this MDL require specific types of empirical evidence to admit Dr. Newman's opinions. Furthermore, as previously demonstrated, Dr. Newman has properly relied on Defendants' own internal documents and data to reach his conclusions.[132] Rather than conducting his own research on the effect of J&J's marketing and advertising practices and opining on the potential effects of the practices over time, he relied on J&J's own marketing research relating to the effect of its advertising and directly cites the copious amounts of J&J collected.[133] Additionally, during his deposition testimony, he cited papers that directly test the impact of trust on perceptions of product risks.

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130 *See In re: Juul Labs, Inc. Mktg. Sales Pracs. & Prods. Liab. Litig.*, Case No. 19-md-02913-WHO, 2022 U.S. Dist. LEXIS 99163, at *73 (2022 WL 1814440) (N.D. Cal. June 2, 2022).

131 *See In re: Juul Labs, Inc. Mktg. Sales Pracs. & Prods. Liab. Litig.*, Case No. 19-md-02913-WHO, 2022 U.S. Dist. LEXIS 99163, at *74 (2022 WL 1814440) (N.D. Cal. June 2, 2022).

132 Newman Report at ¶ 10; Newman Report, Ex. B - References.

133 Newman Report, ¶¶ 12-56; 58-72; 77-81; 84-91.

B. Drs. Sage and Plunkett's Opinions about the Safety of Talc Are Reliable

1. Sage

Despite Defendants' assertions that Dr. Sage offers "ruminations about general causation,"[134] Dr. Sage explicitly states in his report and deposition that he is not offering any general causation opinions regarding whether talcum powder products cause ovarian cancer.[135] Defendants further criticize Dr. Sage for not performing a Bradford Hill analysis. But, again, Dr. Sage is not offering opinions on general causation, and therefore he would have no reason to perform a Bradford Hill analysis. Dr. Sage discusses the scientific literature, including opinions by Plaintiffs' other experts, as part of his broader discussion and opinions related to regulatory practices and standards.

Dr. Sage "did a sufficient review of the scientific literature on which to base [his] opinions,"[136] and "relied on scientific conclusions of scientific experts' published literature."[137] This provided him with a "context that collectively forms the basis for [his] opinions."[138]

Dr. Sage is allowed to rely on other experts in forming his opinions, and Dr.

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134 Defs.' Mot. at 32.
135 Sage Report at 2; Sage 2021 Dep. at 396:5-6.
136 Sage 2021 Dep. at 125:5-6.
137 *Id.* at 123:5-7.
138 *Id.* at 123:17-18; *see also* Appendix 1 to Sage Report (Nov. 14, 2023).

Sage was not required to perform a Bradford Hill analysis to speak about general concepts in the scientific literature. Thus, Defendants' limited arguments against Dr. Sage do not hold water.

2. Plunkett

Dr. Plunkett is not testifying as to causation but only as to risk. Therefore, she performed a Risk Assessment based upon the weight-of-the-evidence, rather than a causation analysis using the Bradford Hill factors. Using Risk Assessment methodology, Dr. Plunkett concludes that the weight-of-the-evidence indicates genital exposure to talcum powder products increases the risk of ovarian cancer.

Dr. Plunkett is not providing a causation opinion; she will not offer an opinion as to whether genital talc use causes cancer.[139] Rather, her opinion, as a toxicologist, is that the weight-of-the evidence indicates that genital exposure to talcum powder products increases the risk of ovarian cancer in women. As Dr. Plunkett states:

> This conclusion is supported by data that includes, but is not limited to the following: (1) the known toxic effects of talc and the other components of talcum powder products; (2) studies that have identified biologically plausible mechanisms for cancer in humans; (3) the likelihood that talc particles can reach the ovaries; (4) the existence of a dose response relationship for toxicity including the risk of cancer; and (5) the large human database that includes studies conducted over a period of 40 years showing a

[139] Plunkett 2023 Dep. 72:15-73:1.

> consistent signal for ovarian cancer in women exposed to talcum powder products.[140]

Dr. Plunkett uses standard and generally accepted methods in all of her work as a toxicologist and pharmacologist, whether for the purposes of litigation or not.[141] The tool she uses for safety assessment is a method known as Human Health Risk Assessment. Toxicology is the scientific core of Risk Assessment, and toxicologists routinely use the Risk Assessment process to assess risks to human health related to exposure to chemicals in the everyday environment.[142] Risk Assessment methodology has been used for decades by governmental bodies to evaluate the safety of chemicals and identify the potential adverse health effects from chemical exposures.[143] There are four basis steps to Risk Assessment, as defined by the National Research Council: hazard identification, dose-response, exposure analysis, and characterization of risks.[144] Risk Assessment is a standard tool used by toxicologists when they are trying to determine if exposure to a chemical or product poses a risk to human health.[145] It is included in Reference Manual on Scientific Evidence, Third Edition (NRC, 2011), which is a resource

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140 Plunkett Report at ¶76, ¶120; Plunkett 2023 Dep. 72:15-73:1.
141 Plunkett Report at ¶11.
142 *Id.* at ¶ 11.
143 *Id*.
144 *Id*.
145 *Id*.

developed for courts when evaluating methodology used by scientists in litigation projects.[146]

Dr. Plunkett's report provides a thorough analysis and application of each step of the Risk Assessment methodology in detail. Defendants are simply unhappy with the result but fail to identify any methodological flaws in her analysis. Dr. Plunkett's opinions on risk are based on a sound methodology, and Defendants arguments should be rejected.

III. DR. KESSLER'S ASBESTOS TESTING AND GEOLOGICAL OPINIONS ARE NOT OUTSIDE HIS AREA OF EXPERTISE

Dr. Kessler's opinions on asbestos in J&J's talcum powder products are offered from the perspective of a former FDA Commissioner and regulatory expert. These opinions require an in-depth understanding of all related scientific disciplines.[147] Understanding the intersection of geology, chemistry, testing methodology, and health effects of toxic substances are a key component of Dr.

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146 *Id*.

147 Dr. Kessler "was interested in looking at this [asbestos] the way FDA would look at this and have to educate themselves from a geological point of view." Kessler Dep. at 170:18-21. Dr. Kessler further explained: "I am not your geology, minerology, microscopist expert" but "I can hopefully [be] helpful as the intersection of those areas with the regulatory world." Kessler Dep. at 76:11-14. "[I]n order to understand the regulations, as is always the case, you have to have an understanding and study the geology. . . . As it relates to regulatory questions and the opinions I've given, I have to be comfortable in that intersection. Kessler Dep. at 76:16-25.

Kessler's background and expertise.[148] As FDA Commissioner, Dr. Kessler had responsibility for the supervision of, among others, the FDA's Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, the Center for Food Safety and Applied Nutrition (which regulated cosmetics), the Center for Biologics Evaluation and Research, and the National Center for Toxicological Research[149]

Dr. Kessler describes this intersection in the following way:

> [T]he unique thing about FDA. FDA finds itself regulating substances that intersects with environmental, geological, mineralogical substances all the time. . . . FDA bring[s] in geologists regularly to understand the interface between [its] regulated products and the potentially hazardous products that are geologically or mineralogically derived."[150]

Many of the documents Dr. Kessler reviewed were, in fact, communications with and discussions concerning the FDA. For example, "[a]t a U.S. Food and Drug Administration Public Meeting: Testing Methods for Asbestos in Talc and

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148 "But that's been my whole life, and that's been my whole training experience." Kessler Dep. at 76:25-77:2.

149 *See* https://www.fda.gov/about-fda/office-chief-scientist/national-center-toxicological-research ("Regulatory science researchers, academia, and other regulatory science research organizations and groups from around the world investigate, learn, and train at the Federal facility. NCTR, FDA's internationally recognized research center, plays a critical role in FDA's mission. The unique scientific expertise of NCTR is critical in supporting FDA product centers and their regulatory roles.")

150 Kessler Dep. at 170:2-171:2.

Cosmetic Products Containing Talc on February 4, 2020, Dr. Bradley Van Gosen from the United States Geological Survey described 'the mineral fibers that can be naturally intergrown with talc and show that their presence or absence is based on the mineral deposit type, that is the geologic conditions that form the talc deposit.'"[151]

In addition, Dr. Kessler brings his deep understanding of the health effects of toxic substances to the issue. This extensive expertise allows him to provide the opinion, "while microscopists and geologists have much to add to our scientific understanding, the failure to adopt a public health approach to asbestos in talc testing, even if that led to overinclusion and false positives, put consumers at risk."[152]

Dr. Kessler's unique background as a former FDA Commissioner with experience in these fields provides him with the expertise to offer his opinions on geology and asbestos.

CONCLUSION

For these reasons, Plaintiffs respectfully request that the Court deny Defendants' Motion to Exclude the expert opinions of Drs. Kessler, Plunkett, Sage, and Newman.

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151 Kessler Report at 23.

152 Kessler Report at 100.

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